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09/432,503	11/02/1999	THOMAS R. CECH	15389-002611	1130
34151	7590	10/04/2007		
TOWNSEND AND TOWNSEND AND CREW LLP			EXAMINER	
8TH FLOOR			ANGELL, JON E	
TWO EMBARCADERO CENTER				
SAN FRANCISCO, CA 94111			ART UNIT	PAPER NUMBER
			1635	
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			10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/432,503

Applicant(s)

CECH ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-57 and 74-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-57, 74-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/25/2007 has been entered.
2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 41-57, 74-82 are currently pending and are examined herein.

Terminal Disclaimer

The terminal disclaimer filed on 7/25/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 09/721,506 and U.S. patents 7,195,911 6,261,836 6,337,200 6,475,789 6,921,664 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 41-57, 74-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

It is noted that instant claim 42 was amended 12/24/2004 to include the limitation that the recombinant polynucleotide can encode a fragment of SEQ ID NO: 2 that contains the telomerase T motif:

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Trp-X₁₂-Phe-Phe-Tyr-X-Thr-Glu-X₁₀₋₁₁-Arg-X₃-Trp-X₇-Ile (SEQ. ID NO: 119)

Applicants asserted in the 12/24/2004 communication that support for the amendment could be found "Presence of sequences bearing or resembling the 'T' motif in functional in functional TRTs of all species is discussed extensively in the text." (See page 8 of the 12/24/2004 communication).

However, upon further consideration, the specification does not appear to provide literal or implicit support for the exact sequence "Trp-X₁₂-Phe-Phe-Tyr-X-Thr-Glu-X₁₀₋₁₁-Arg-X₃-Trp-X₇-Ile". Furthermore, SEQ ID NO: 119 does not match the indicated sequence, as SEQ ID NO: 119 is the 41 amino acid sequence: Lys Ile Tyr Phe Leu Ile His Ser Thr Ser Ile Ala Ala Leu Val Val Thr Arg Lys Asp Ala Lys His Cys Asn Leu Ala Arg Asn Arg Leu His Cys Leu Phe Gln Ser Cys Lys Asn Asn, which does not appear to comprise the sequence as indicated in the claim. Therefore, although SEQ ID NO: 119 may not be new matter, the sequence "Trp-X₁₂-Phe-Phe-Tyr-X-Thr-Glu-X₁₀₋₁₁-Arg-X₃-Trp-X₇-Ile" appears to be new matter.

Should Applicants traverse this rejection, they are asked to indicate the specification location of the disclosure (by page and line number) where support can be found.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 41-57, 74-82 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 41-57, 74-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As indicated above, claim 42 encompasses a recombinant polynucleotide that encodes a fragment of SEQ ID NO: 2 that contains the telomerase T motif:

Trp-X₁₂-Phe-Phe-Tyr-X-Thr-Glu-X₁₀₋₁₁-Arg-X₃-Trp-X₇-Ile (SEQ. ID NO: 119)

However, SEQ ID NO: 119 (see CRF and Paper Sequence Listing) does not match the indicated sequence, as SEQ ID NO: 119 is the 41 amino acid sequence: Lys Ile Tyr Phe Leu Ile His Ser Thr Ser Ile Ala Ala Leu Val Val Thr Arg Lys Asp Ala Lys His Cys Asn Leu Ala Arg Asn Arg Leu His Cys Leu Phe Gln Ser Cys Lys Asn Asn. Therefore SEQ ID NO: 119 is not “Trp-X₁₂-Phe-Phe-Tyr-X-Thr-Glu-X₁₀₋₁₁-Arg-X₃-Trp-X₇-Ile” as claim 42 indicates. Since the sequence explicitly indicated in the claim and SEQ ID NO: 119 are not exactly the same, claim 42 and all claims that depend on claim 42 are indefinite as it is not clear which SEQ ID NO (if any) the indicated sequence refers to.

Allowable Subject Matter

7. Claims 48-51 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraph, set forth in this Office action and to include all of the

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limitations of the base claim and any intervening claims. That is, amending claims such that claim 42 did not comprise the new matter and indefinite limitations and such that claim 42 was included the limitation that the polynucleotide comprises a sequence which encodes the amino acid sequence that is SEQ ID NO: 2 (such as in instant claim 48) would obviate the rejections of record and the claims would be allowable. It is noted that instant claims 48-52 are currently properly rejected under 35 U.S.C. 112, 1st and 2nd paragraph as they must encompass all of the limitations of the base claim, including the new matter and indefinite limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
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